

**Amendment and Response**

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Serial No.: 09/814,257

Confirmation No.: 6204

Filed: 21 March 2001

For: PRIMERS FOR USE IN DETECTING BETA-LACTAMASES

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**Remarks**

The Office Action mailed May 19, 2003 has been received and reviewed.

Claims 17, 43, 49, and 53, having been amended, and claim 54 having been added, the pending claims are claims 12-17, 39-44, 47-49, and 51-54.

Claims 17 and 49 have been amended to recite primers specific for nucleic acid characteristic of the OXA-family of beta-lactamase enzymes, wherein the enzyme is found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae*, *Citrobacter freundii*, *Serratia marcescens*, *Escherichia coli*, *Providencia spp.*, *Proteus mirabilis*, *Yersinia enterocolitica*, and combinations thereof, excluding OXA-1. Claim 17 has been further amended to recite a method including analyzing the separated amplified product for a region characteristic of a beta-lactamase found in a Gram-negative bacterium selected from the group consisting of *Enterbacter cloacae*, *Citrobacter freundii*, *Serratia marcescens*, *Escherichia coli*, *Providencia spp.*, *Proteus mirabilis*, *Yersinia enterocolitica*, and combinations thereof.

Claims 43 and 53 have been amended to recite methods including primers specific for nucleic acid characteristic of specifically recited OXA-family beta-lactamase enzymes.

New claim 54 has been added to claim a method for identifying a beta-lactamase in a clinical sample including primers specific for nucleic acid characteristic of the OXA-family of beta-lactamase enzymes, wherein the enzyme is found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae*, *Citrobacter freundii*, *Serratia marcescens*, *Providencia spp.*, *Proteus mirabilis*, *Yersinia enterocolitica*, and combinations thereof, and further including analyzing the separated amplified product for a region characteristic of a beta-lactamase found in a Gram-negative bacterium selected from the group consisting of *Enterbacter cloacae*, *Citrobacter freundii*, *Serratia marcescens*, *Providencia spp.*, *Proteus mirabilis*, *Yersinia enterocolitica*, and combinations thereof.

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Support for these amendments is found in the specification at, for example, page 3, lines 19-20, line 27, page 4, lines 14-23, and in the claims as filed and as currently amended.

No new matter has been added as a result of these amendments.

Reconsideration and withdrawal of the rejections in view of the above amendments and the following comments are respectfully requested.

**Allowed Claims**

Applicants thank the Examiner for indicating that claims 12-16 and 51 are allowable as SEQ ID Nos: 34-43 are free of the prior art, and that claims 52 and 53 would be allowable if the rejection under 35 U.S.C. §112, second paragraph, is overcome.

**Claim Objections**

The Examiner objected to claim 53, alleging the informality that the phrase "the OXA family beta-lactamase enzymes designated as OXA-10, 11, or 14" should be recited as, "the OXA family beta-lactamase enzymes designated as OXA-5, 6, 7, 10, 11, 13, or 14" since SEQ ID NO: 38 and SEQ ID NO: 39 can be used to amplify OXA-5, 6, 7, 10, 11, 13, and 14 beta-lactamase enzymes in view of originally filed claims 43 and 44.

Applicants submit that the amendment to claim 53 made herein overcomes the Examiner's objection. Reconsideration and withdrawal of this objection is, therefore, respectfully requested.

**The 35 U.S.C. §112, First Paragraph, Rejection**

The Examiner rejected claims 17, 39-44, and 47-49 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner

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alleged that the specification does not adequately describe OXA-16 and 17, as recited in claims 17, 39-44, and 49.

Applicants do not agree that the exclusion of matter that is not claimed should be considered as new matter. However, solely for the purpose of facilitating prosecution of the present application, Applicants have amended independent claims 17 and 49 to remove the language excluding OXA 10, 11, 14, 16, and 17. Applicants respectfully assert these amendments overcome the Examiner's rejection under 35 U.S.C. § 112, first paragraph to independent claims 17 and 49, and also overcomes the rejection of claims 39-44, 47, and 48, directly or indirectly dependent on claim 17. Therefore, reconsideration and withdrawal of the rejection is respectfully requested.

**The 35 U.S.C. §112, Second Paragraph, Rejections**

The Examiner rejected claims 17, 39-44, 47, 48, 52, and 53 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

Furthermore, Applicants respectfully point out that while the Examiner rejected claims 17, 39-44, 47, 48, 52, and 53 under 35 U.S.C. §112, second paragraph, only claims 17, 44, 52, and 53 were specifically discussed in the present Office Action. Applicants respectfully assert that in view of the comments herein, in addition to independent claims 17, 52, 53, and dependent claim 44, claims 39-43, 47, and 48, directly or ultimately dependent on claim 17, are also not indefinite under 35 U.S.C. §112, second paragraph.

**Claims 17, 52, and 53**

Claims 17, 52, and 53 were rejected as vague and indefinite in view of the phrase "wherein one primer of the pair is complements [*sic*] to at least a portion of the beta-lactamase nucleic acid in the sense strand and the other primer of each pair is complementary to

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at least a portion of the beta-lactamase nucleic acid in the antisense strand," alleging that it is unclear that "the pair" and "each pair" in the phrase are directed to the same pair of oligonucleotide primer or not. Applicants respectfully traverse this rejection.

Applicants do not agree that claims 17, 52, and 53 as recited are indefinite, and submit that one skilled in the art would understand from a reading of the claim that the "each pair" recited in the claim refers to the pair previously recited. The claims recite "a pair," subsequently reciting "the pair." No other "pair" is specifically recited, and in the context of the claim it is submitted that one skilled in the art would understand that the recital of "each pair" refers to "the pair" previously recited. Reconsideration and withdrawal of the rejection is respectfully requested.

The Examiner further rejected claims 17, 52, and 53 as vague and indefinite in view of the phrase "wherein each extension product after separation from the beta-lactamase nucleic acid serves as a template for the synthesis of an extension product for the other primer of each pairs [*sic*]," alleging that it is unclear what the phrase means. Applicants respectfully traverse this rejection.

Applicants do not agree that these claims as written are indefinite, and that one skilled in the art, upon a complete reading of the claim and with an understanding of the disclosure of the specification, would understand the claimed invention. The Examiner admits that it is known that during PCR, each extension product after separation from its complementary strand (its template) serves as a template for synthesis of another extension product using a primer that is complementary to each extension product. Claims 17, 52, and 53 recite, "wherein each extension product after separation from the beta-lactamase nucleic acid serves as a template for the synthesis of an extension product for the other primer of each pair," and also recite, "wherein one primer of the pair is complementary to at least a portion of the beta-lactamase nucleic acid in the sense strand, and the other primer of each pair is complementary to at least a portion of the beta-lactamase nucleic acid in the antisense strand." That is, from a reading of the

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claims and the specification, one skilled in the art would understand, for example, that the extension product separated from the beta-lactamase serves as a template for the synthesis of an extension product for the other primer of each pair, which is complimentary to the one primer of the pair. Applicants submit, therefore, that the claims as written are not indefinite, and reconsideration and withdrawal of the rejection is respectfully requested.

**Claim 44**

Claim 44 was rejected as vague and indefinite in view of claim 17, original filed claim 43, and newly added claim 53, alleging that claim 17 and claim 44 do not correspond to each other and claim 44 does not further limit claim 17.

Applicants contend that in view of the amendments to the claims made herein, this rejection has been overcome. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

**Summary**

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested.

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The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 22<sup>nd</sup> day of September, 2003, at 5:50 pm (Central Time).

By: Name: KATHLEEN L. FRANKLIN